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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,238	06/04/2001	Jens Chr. Jensenius	09011-002003	6910

1444 7590 04/11/2005

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/874,238	JENSENIUS ET AL.	
Examiner	Art Unit	
David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23, 26, 37, 41, 43-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 19-23, 26, 37, 41 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/06/04 has been entered.

Following entry of the amendment of 12/6/04 claims 18-23, 26, 37, 41 and 43-45 are pending and under examination.

The drawings are objected to because, while they have been printed in USPGPUB 2002/0082209 (and will be printed as such in a granted patent, if not replaced), the characters are not readable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office Action. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the

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applicant will be notified and informed of any required corrective action in the next Office action.

The disclosure is objected to because of the following informalities: at page 1, there is no continuation data referring to parent 09/054,218 and its current status; at page 54, line 11 is "respectively" correct?.

Appropriate correction is required.

The disclosure is large. Except for the above noted objections to the disclosure, the examiner will refer to its contents by para. number in US PGPUB 2002/0082209.

Regarding rejections of record in the final rejection of 3/8/04, the examiner notes the following:

- 1) The amendment of claim 26 has overcome the 112, first paragraph rejection.
- 2) The 102(a) rejection over Thiel et al has been overcome by the addition of Willis as an inventor and by the cancellation of claim 40 (reciting SEQ ID NO:2).

It is noted that a Request to correct inventorship with a processing fee was filed on 10/5/04.

Attached thereto is a statement from Willis, who is the added inventor, and a newly executed oath by the actual inventors.

The Request indicates that there has been no assignment.

Also on 12/6/04 inventors Jensenius and Thiel filed 1.132 declarations, which further explain the roles of co-authors of Thiel et al who are not inventors.

Since all requirements of 37 CFR 1.48(a) have been met the 102(a) rejection over Thiel et al has been withdrawn.

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New grounds of objection and rejection are stated infra.

Claim 44 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 44 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 44 "the MASP-2 polypeptide" lacks antecedent basis, in claim 19.

Claims 19-23, 26, 37, 41 and 43-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was not in possession of antibodies that specifically bind to the genus of MASP-2 antigens.

Specifically, the examiner finds the disclosure to be devoid of a description of the genus of MASP-2 antigens because only one species of such, from a human, has been described. The disclosure gives no indication of how much variability there may be in the structural features of MASP-2 antigens from different species.

The disclosure also indicates that there is a MASP – 1 antigen of humans (sequence shown in Fig. 2) that has 45% identity and 52% similarity in its sequence, in

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comparison to the instant MASP-2; see [0147]. The disclosure, however, provides no information as to how much variability there may be in the structural features of MASP-1 antigens from different species.

Given the fact that MASP-1 and MASP-2 are proteins having a degree of identity and similarity in sequence, and given the fact that there is information as to how much sequence variation there is among different species for either of these antigens, and given that fact that MASP-1 and MASP-2 have similar functions that can be related to the presence of like domains (see [0146]); it is not clear that one obtaining "MASP antigen" from a species other than human would know whether the "MASP antigen" is MASP-1 or MASP-2, C1r or C1s (to which MASP-1 and MASP-2 are related, as set forth in para. [0146]), or even to another uncharacterized MASP antigen (In fact a MASP-3 of humans has been later obtained; see US PGPUB 2003/0186319).

Furthermore, the examiner finds that, with its broadest functional definition, the term "MASP-2" does not even need to have an art recognizable function, such as proteolysis activity. A MASP-2 polypeptide of the instant invention need only have antigenic activity such that it "serves as an antigen for the production of antibodies that specifically bind to MASP-2" (para. [0033]). This as a circular definition; applicant is attempting to "define an unknown by its binding affinity to another unknown." See Noelle v. Lederman 69 USPQ2d at page 1514. By virtue of attempting to encompass much by his definitions, applicant has ended up describing nothing but what is exemplified as human MASP-2.

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Since the one species of MASP-2 from a human does not provide for an adequate exemplification of the genus of MASP-2 antigens, there is no adequate description of the antibodies directed to the genus. The instant fact situation precisely follows that of *Noelle v. Lederman* 69 USPQ2d 1508.

Since claim 18 is limited to antibodies obtained by administering human MASP-2 to a non-human animal, claim 18 has not been included in the above rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644

Saunders/LR

March 24, 2005